Pfizer Global Regulatory Affairs Pfizer Inc. 400 Arcola Road Collegeville, PA 19426



Global Product Development

11 August 2021

Marion Gruber, Ph.D. Director Office of Vaccines Research and Review Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Avenue WO71, G112 Silver Spring, MD 20993-0002 THIS DOCUMENT CONTAINS CONFIDENTIAL AND/OR TRADE SECRET INFORMATION THAT IS DISCLOSED ONLY IN CONNECTION WITH THE LICENSING AND/OR REGISTRATION OF PRODUCTS FOR PFIZER INC OR ITS AFFILIATED COMPANIES. THIS DOCUMENT SHOULD NOT BE DISCLOSED OR USED, IN WHOLE OR IN PART, FOR ANY OTHER PURPOSE WITHOUT THE PRIOR WRITTEN CONSENT OF PFIZER INC.

Re: BLA 125742

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Response to FDA's 05 August 2021 Information Request Regarding Facilities

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 18 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals \geq 16 years of age.

On 05 August 2021, the Agency sent an Information Request regarding facilities. The requested information is provided in Response to 05 Aug 2021 FDA Information Request - Facilities Questions in Module 1.11.1.

Reference is also made to the submission on 30 July 2021 in response to CBER's 26 July 2021 Information Request regarding manufacturing and equipment to Pfizer, received via email from Laura Gottschalk, PhD (CBER/OVRR). Specifically, this response also includes a follow-up to response 16e on information for portable tank (b) (4).

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at elisa.harkinstull@pfizer.com.

Marion Gruber, Ph.D., Director BLA 125742

Page 2 of 2 11 August 2021

Sincerely,

Elisa Harkins Global Regulatory Lead Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D. CC: Michael Smith, Ph.D. CC: Laura Gottschalk, Ph.D.